PUBLIC HEALTH COUNCIL

Meeting of the Public Health Council, Tuesday, July 20, 1999, 10:00 A.M., Massachusetts Department of Public Health, 250 Washington Street, Floor 2, Boston, Massachusetts. Present were: Dr. Howard K. Koh (Chairman); Dr. Clifford Askinazi; Mr. Manthala George Jr.; Ms. Shane Kearney Masaschi; Mr. Albert Sherman; Ms. Janet Slemenda; Mr. Joseph Sneider; Dr. Thomas Sterne; and Mr. Bertram Yaffe was absent. Also in attendance was Ms. Donna Levin, General Counsel.

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Chairman Koh announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance, in accordance with the Massachusetts General Laws, Chapter 30A, Section 11A 1/2. In addition, Dr. Koh announced that the August meeting has been rescheduled from August 24 to August 17, 1999 and further that today's docket has been revised to add docket item 3b -- Promulgation of amendments to 105 CMR 180.000: The Operation, Approval, and Licensing of Clinical Laboratories.

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The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Dr. Deborah Klein-Walker, Assistant Commissioner, Bureau of Family and Community Health; Ms. Liz Metallinos-Katsaras, Project Manager, Nutrition and Chronic Disease Unit, Office of Statistics and Evaluation, Bureau of Family and Community Health; Ms. Kate Alich, Diabetes Control Program Coordinator, Bureau of Family and Community Health; Ms. Joyce James, Director, Determination of Need Program; and Attorney Carl Rosenfield, Deputy General Counsel, Office of the General Counsel.

RECORDS OF THE PUBLIC HEALTH COUNCIL MEETINGS OF MARCH 30, 1999 AND APRIL 27, 1999:

Records of the Public Health Council meetings of March 30, 1999 and April 27, 1999 were presented to the Council. After consideration, upon motion made and duly seconded, it was voted (unanimously): That, records of the Public Health Council Meeting of March 30, 1999 and April 27, 1999, copies of which had been sent to the Council Members for their prior consideration, be approved, in accordance with Massachusetts General Laws, Chapter 30A, Section 11A 1/2.

PERSONNEL ACTIONS:

In a letter dated June 18, 1999, Howard K. Koh, Commissioner, Department of Public Health, recommended approval of the appointment of Joanne Calista to Program Manager VI (Director of Health Services), HIV/AIDS Bureau. Supporting documentation of the appointee's qualifications accompanied the recommendation. After consideration of the appointee's qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Commissioner of Public Health, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the appointment of Joanne Calista to Program Manager VI (Director of Health Services) be approved.

In a letter dated June 18, 1999, Howard K. Koh, Commissioner, Department of Public Health, recommended approval of the appointment of Anne McHugh to Program Manager VI (Director, Primary Care Services), Bureau of Family and Community Health. Supporting documentation of the appointee's qualifications accompanied the recommendation. After consideration of the appointee's qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Commissioner of Public Health, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the appointment of Anne McHugh to Program Manager VI (Director of Primary Care Services) be approved.

In a letter dated July 8, 1999, Blake Molleur, Executive Director, Western Massachusetts Hospital, Westfield, recommended approval of the reappointment of Paul F. Haley, M.D. to the consulting medical staff of Western Massachusetts Hospital. Supporting documentation of the appointee's qualifications accompanied the recommendation. After consideration of the appointee's qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Executive Director of Western Massachusetts Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the following reappointment to the consulting medical staff of Western Massachachusetts Hospital be approved:

NAME	**RESPONSIBILITY**	**MEDICAL LICENSE NO.**
Paul F. Haley, M.D.	Psychiatry	81763

In letters dated July 7, 1999, Katherine Domoto, M.D., Associate Executive Director for Medicine, Tewksbury Hospital, Tewksbury, recommended approval of an appointment and reappointments to the provisional affiliate, consultant and active medical staffs of Tewksbury Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Associate Executive Director for Medicine of Tewksbury Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the appointment and reappointments to the provisional affiliate, consultant and active medical staffs of Tewksbury Hospital be approved for a period of two years beginning July 1, 1999 to July 1, 2001:

APPOINTMENT	STATUS/SPECIALTY	MEDICAL LICENSE NO.
David Fishbein, M.D.	Psychiatry	29761

REAPPOINTMENT	STATUS/SPECIALITY	MEDICAL LICENSE NO.
Bruce Price, M.D.	Consultant Staff/ Neurology	49559
Khatija Gaffar, M.D.	Active Staff/Internal Medicine	53316
Alice Graham-Brown, M.D.	Active Staff/Psychiatry	75005
Syed Rahman, M.D.	Active Staff/Internal Medicine	73277

In a letter dated July 12, 1999, Robert D. Wakefield, Jr., Executive Director, Lemuel Shattuck Hospital, recommended approval of the initial appointments and reappointments to the consultant and active medical staffs of Lemuel Shattuck Hospital, Jamaica Plain. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees'qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Executive Director, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the following appointments and reappointments to the medical staff of Lemuel Shattuck Hospital be approved:

APPOINTMENTS	STATUS/SPECIALTY	MEDICAL LICENSE NO.
Rafael Alteri, M.D.	Consultant/Radiology	157787
Rafeeque A. Bhadelia, M.D.	Consultant/Radiology	78973
Timothy Pace, M.D.	Active/Psychiatry	150244
Julia Salmon, M.D.	Active/Internal Medicine	154943
Mahmood H. Sharfi, M.D.	Active/Psychiatry	151691

REAPPOINTMENTS	STATUS/SPECIALTY	MEDICAL LICENSE NO.
Alexey Makogonov, M.D.	Active/Internal Medicine	151220

STAFF PRESENTATION:

"The Burden of Diabetes in Massachusetts 1993-1995"

Dr. Deborah Klein-Walker, Assistant Commissioner, Bureau of Family and Community Health, made introductory remarks. The presentation was made by Liz Metallinos-Katsaras, Project Manager, Nutrition and Chronic Disease Unit, Office of Statistics and Evaluation, and Kate Alich, Diabetes Control Program Coordinator, Bureau of Family and Community Health. Staff noted in part, "This report summarizes the burden of diabetes in the Commonwealth of Massachusetts between 1993 and 1995. It draws on a variety of data sources that are regularly collected at the state and federal level, and which comprise the Massachusetts Diabetes Control Program's surveillance system. The report addresses the prevalence of diabetes, its associated morbidities, and the cost of health care spent on hospitalizations related to the disease. This report is intended to provide information to community health care providers that facilitates needs assessment and program planning and makes information about diabetes and its effect on life in Massachusetts available to those for whom it is of interest. Some excerpts from the report follow:

- Diabetes is a disorder in which the body either does not produce or does not respond effectively to its own insulin, a hormone produced by the pancreas. Most of the food we eat is broken down into a simple sugar called glucose which the body's cells use for energy. Insulin must be present for glucose to enter the cells. A lack of insulin results in high blood glucose levels that can lead to both short-term and long-term diabetes complications (NIH, 1994). Short-term complications may develop if daily control of the disease is inadequate. These include hyperglycemia and ketoacidosis. In contrast, long-term complications, which develop gradually over time, are caused mainly by damage to blood vessels. These complications include heart disease, stroke, lower extremity amputations, kidney disease, blindness, and nerve damage (NIH, 1994).

- Diabetes is serious, common, and costly. Estimates suggest that approximately 244,500 residents of Massachusetts have been diagnosed with diabetes, while as many as 122,200 additional residents have the disease, yet remain undiagnosed. Diabetes disproportionately affects racial and ethnic minorities, the elderly, and the obese. The estimated prevalence of diabetes among non-Hispanic blacks (6.9%) and Hispanics (5.4%) was greater than that reported for non-Hispanic whites (3.8%). Residents of the Commonwealth who are age 75 or older are more than twice as likely to have diabetes as those between the ages of 45 and 64. An estimated 8% of obese individuals have the disease, compared to 5% of those who are overweight and 3% of those who are of normal weight.

- Diabetes was the sixth leading cause of death listed on death certificates in Massachusetts during 1995. As with the estimated prevalence of the disease, the likelihood of mortality and morbidity associated with the disease increases with age. The diabetes mortality rate of the Massachusetts population also varied by sex and race. Every year between 1990 and 1995 males had a higher diabetes mortality rate than females did. Among non-Hispanic

blacks and Hispanics in the Commonwealth between 1993 and 1995, a greater percentage of all deaths were attributable to diabetes than among non-Hispanic whites.

- Diabetes is an independent risk factor for heart disease and stroke. In Massachusetts between 1993-1995, diseases of the circulatory system were the most common reason for hospitalization among diabetics, and were listed as the primary diagnosis for 34% of diabetics who were hospitalized. Ischemia was listed as the primary diagnosis for 9.4%, and stroke was listed as the primary diagnosis for 4.8% among diabetics who were hospitalized.

- Ketoacidosis, renal disease and nontraumatic lower extremity amputations disproportionally affect diabetics. These three complications follow cardiovascular disease as the next most common reasons for hospitalization in Massachusetts from 1993-1995.

- Diabetes is also one of the leading causes of adult blindness in Massachusetts. During 1993-95, a total of 1,145 residents were newly blind from diabetes. Among all new cases of blindness registered in Massachusetts during 1995, diabetic retinopathy was the single most frequently reported cause of blindness among those ages 23-65.

- Hospital discharge data reinforce evidence of racial disparities with respect to those who experience diabetes complications. Among all non-Hispanic black and Hispanic diabetic individuals who were hospitalized, a greater proportion were hospitalized for ketoacidosis and end-stage renal disease (ESRD) as compared to non-Hispanic whites. The frequency of diabetic complications in some racial/ethnic groups could be attributable to several factors. These include but are not limited to: delay in diagnosis and treatment, lifestyle factors such as smoking, socioeconomic factors such as lack of insurance, and psychosocial factors such as denial of the disease.

- It is estimated that diabetes-related hospitalizations cost residents of Massachusetts over $425 million during 1995 alone. Although regional estimates vary, each diabetic hospitalization cost an average of $10,217 and required an average hospital stay of 6.8 days during 1995. A subset of diabetes-related hospitalizations, categorized as preventable by the Massachusetts Division of Health Care Finance and Policy, cost an average of $20.7 million annually. Among all preventable hospitalizations diabetes was ranked as the fifth most expensive. Medicare paid for the largest percentage (43.6%) of these hospitalizations, resulting in more than $9 million in expenditures.

- Within Massachusetts, the Diabetes Control Program (DCP) is working to reduce the burden of this disease in the community via health systems, health communications and diabetes surveillance initiatives whose ultimate goal is to improve the quality of care provided to people with diabetes. The DCP is involved in a wide variety of activities focused on improving control of diabetes and its complications.

FINAL REGULATIONS:

REQUEST FINAL PROMULGATION OF EMERGENCY AMENDMENT TO DETERMINATION OF NEED REGULATIONS 105 CMR 100.000 GOVERNING MANDATORY TERMS AND CONDITIONS:

Ms. Joyce James, Program Director, Determination of Need Program, presented the amendment to the Council. She said in part, "The amendment retains the January 1, 2000 expiration date for determinations of any convalescent, nursing and rest home projects but eliminates the requirement that facilities be licensed by that date. The amendment was prompted by the fact that holders of BANYLs (Beds Approved but Not Yet Licensed) have encountered difficulties in securing and maintaining capital financing. These difficulties have occasioned delays in the commencement of certain projects and have called into question the ability of holders to complete the projects and have the facilities licensed by the January 1 deadline. The emergency adoption of the amendment was necessary to ensure that projects that have commenced can receive continued financing. This amendment will avoid a situation where a facility is in the process of being built but will be unable to retain continued financing for completion due to the January 1, 2000 licensing requirements currently in effect. A public hearing had been held on May 7, 1999. Two people attended the hearing neither of whom testified. No written comments were submitted on the amendment."

After consideration, upon motion made and duly seconded, it was voted: (unanimously): that the **Request for Final Promulgation of Emergency Amendment to Determination of Need Regulations 105 CMR 100.000 Governing Mandatory Terms and Conditions** be approved; that a copy be forwarded to the Secretary of the Commonwealth; and that a copy of the amendment be attached and made a part of this record as **Exhibit No. 14,656.**

REQUEST PROMULGATION OF AMENDMENT TO 105 CMR 180.000: THE OPERATION, APPROVAL, AND LICENSING OF CLINICAL LABORATORIES – SPECIAL PROJECTS:

Attorney Carl Rosenfield, Deputy General Counsel, presented the regulations to the Council, accompanied by Ms. Doris DeGraves, Director, Clinical Laboratory Program. Staff noted, "On April 27, 1999, the Council voted to approved the adoption of the amendment as an emergency regulation. The Regulation was filed with the Secretary of State on April 29, 1999 and in compliance with the provisions of M.G.L.c.30A a public hearing was held on June 16, 1999. No written comments received. The amendment allows for the approval of innovative special projects that, although not meeting the letter of the licensing regulations, would be of benefit to the public health. At the April 27, 1999 Council meeting, staff pointed out that the clinical laboratory regulations, unlike a number of the Department's other facility licensing regulations, lacked a provision allowing for the approval of special projects. The need for such a regulation became apparent when the Department received a proposal from Dr. William Castelli of the Framingham Cardiovascular Institute (the Institute). The Institute proposed a project that would screen and identify those tenth grade high school students who may be likely to develop an

elevated cholesterol profile and the risks associated with such a condition. Staff reviewed the proposal and found the initiative to be of merit. However, the proposal is not fully compliant with the present regulations in ways that have no bearing on the accuracy and quality of the testing to be performed. The regulation allows the Department the flexibility to approve this and other worthwhile programs."

Staff further noted, "The emergency adoption of the proposed amendment allowed the Institute to implement its program during the school year and begin the process of educating teenagers about the long term health risks and potential health consequences that result from poor dietary habits, lack of exercise and cigarette smoking. The final adoption of the regulation will allow the consideration and approval of other meritorious innovative projects."

After consideration, upon motion made and duly seconded, it was voted: (unanimously) to approve **Promulgation of Amendment to 105 CMR 180.000: The Operation, Approval, and Licensing of Clinical Laboratories – Special Projects*;*** that a copy of the amendment be forwarded to the Secretary of the Commonwealth; and that a copy be attached and made a part of this record as ***Exhibit No. 14,657.***

DETERMINATION OF NEED -- COMPLIANCE MEMORANDUM:

PREVIOUSLY APPROVED DoN PROJECT NO. 5-1389 OF CATHOLIC MEMORIAL HOME INC.:

Ms. Joyce James, Director, Determination of Need Program, presented the request of previously approved Project No. 5-1389 of Catholic Memorial Home Inc. She said in part, "…Catholic Memorial Home is requesting a significant change to increase the capital expenditure and the present number of beds for Project No. 5-1389. The changes include increases in the maximum capital expenditure from $14,709,572 (May 1996 dollars) to $17,924,627 (June 1998 dollars) and the number of beds to be replaced from 180 to 184. The additional $2,839,225 (June 1998 dollars) increase above inflation requested by the holder includes $2,363,311 in construction costs and $475,914 in financing costs. The increase in construction costs include $203,480 for land development, $1,711,096 for renovation and new construction, $225,000 for asbestos abatement and $335,000 for phased construction, less a $111,265 decrease for major movable equipment and pre- and post-filing planning and development. Supporting documentation submitted with the request indicates cost increases are due to site development problems, compliance with February 28, 1998, State Building Code 6th edition requirements, building configuration, asbestos abatement, phased in construction and a change in project financing. The holder reports that the amended MCE is based on estimates obtained from two independent firms with experience in facility replacement and renovation in the Fall River area. The holder further reports that the firms, Daedalus Projects, Inc. and the Aspen Group/Columbia Construction Company, based their estimates on detailed architectural plans, site analysis and soil borings, engineering studies and asbestos survey. The holder further states that the precipitous slope of the site requires additional costs for land development in order to provide extra space for parking, service and outdoor recreational areas, and new mechanical and support systems. Additionally, preliminary soil borings indicated ledges, boulders and water tables under the site,

requiring additional costs for excavation, re-grading and construction and foundation water proofing to comply with applicable local requirements. The holder reports that both the renovated facility and new constructed addition must conform to the new State Building Code seismic design requirements, which became effective after the application was filed in May, 1996. This, the holder asserts, will increase costs for steel reinforcements, masonry construction, hangers and supports for mechanical and electrical equipment. The holder further reports that the configuration and structural limitations of the facility create numerous inefficiencies and physical plant deficiencies which, to comply with licensure standards and ADA (Americans with Disabilities Act), require higher renovation cost/GSF than is usually allowed by the Department. Additionally, construction of a 10,500 GSF "North Addition," to the A-wing of the facility is needed to enhance facility efficiency by creating optimally sized and more cost effective nursing units. Staff notes that the "North Addition" is included in the GSF for new construction approved in the original DoN. The holder adds that the 10,500 GSF new construction will be costly, requiring more than typical work to tie in the four existing floor levels and provide multiple mechanical and support systems on each floor."

Staff continued, "The holder states that a comprehensive inspection of the facility revealed substantial asbestos which must be abated to implement the project and protect residents' health and safety. The phased construction was considered to minimize disruptions to residents' living conditions and the staff's ability to deliver care. The phased construction requires additional construction cost to maintain temporary redundant systems, one to continue operations in the existing building and the other for the new wing. The holder notes that increasing the number of replacement beds by four will help to reduce the number of beds per room and increase the size of rooms to meet new construction standards. The holder explains that the additional renovation and new construction described above were unforeseen at the time the application was filed. Standards for DoN Applications require only schematic line drawings for new construction and renovation. It was not until detailed architectural plans and specifications were developed for final plan approval by the Department that the holder became aware of the problems that initiated this significant change to the project's MCE. Staff notes that the increase cost/GSF in new construction and renovation also was not anticipated at the time the application was filed. The applicant apparently did not know the structural limitations of the building, including the substantial presence of asbestos, at the time the application was filed and the cost to bring it into compliance with local and state building codes and construction standards. The original DoN did not include costs for securing financing because the project was to be financed with a loan from the Roman Catholic Diocese of Fall River which owns the facility. According to the holder, this financing approach is no longer feasible and other financing options comparable to other nursing home facilities must now be pursued. The holder's estimated cost of securing financing was based on discussions with two potential lenders familiar with the project."

"In reviewing the holder's request," said staff, "Staff has determined whether the requested additional costs were reasonable in light of past decisions, were not foreseeable at the time the application was filed and were beyond the holder's control. Consistent with the Council's past decisions, staff finds that the additional costs could not have been reasonably foreseen and were not reasonably within the control of the holder. Staff, however, notes that the holder used a 4.24% inflation adjustment factor which exceeds the 3.07% calculated by staff. Therefore, staff

has reduced the requested construction costs by $184,933. Staff recommends approval with a condition to increase the MCE to $17,739,694 (June 1998 dollars). The total GSF approved for this project is 134,049 including 61,601 GSF for renovation and 72,448 GSF for new construction."

After consideration, upon motion made and duly seconded, it was voted: (unanimously) to approve the request by **Previously Approved Project No. 5-1389 of Catholic Memorial Home, Inc.** to increase the MCE to $17,739,694 (June 1998 dollars). The total GSF for this project is 134,049 including 61,601 GSF for renovation and 72,448 GSF for new construction. The MCE is itemized as follows:

Construction Costs:

Land Acquisition		0
Land Development		$940,495
Construction Contract	\	
Fixed Equipment not in Contract	>	14,127,314
Architectural & Engineering Costs	/	
Site Survey and Soil Investigation	/	
Major Movable Equipment		954,000
Pre-Post-Filing Planning & Development		53,000
Other: Asbestos Abatement		222,367
Other: Phased Construction		331,080
Total Construction Costs:		**$16,628,256**

Financing Costs:

Net Interest Expense During Construction	$607,042
Costs of Securing Financing	504,396
Total Financing Costs:	1,111,438

Total Maximum Capital Expenditure:	**$**	**17,739,694**

This amendment is subject to the following condition:

1. All other conditions attached to the original and amended approval of this project shall remain in effect.

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The meeting adjourned at 11:05 P.M.

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Howard K. Koh, M.D., M.P.H.
Chairman

LMH

MINUTES OF THE PUBLIC HEALTH COUNCIL

MEETING OF JULY 20, 1999

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH